

Rapid Acceleration of Diagnostics Technology (RADx Tech)

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging & Bioengineering (NIBIB)


[illegible]

When to Test

New features launched in the COVID-19 Testing Impact Calculator include a tool to help organizations plan for and demonstrate how testing and other mitigation measures can



Webinar Series

 This webinar series hosted by POCTRN provides information on RADx Tech/ATP program activities. Register for upcoming events or watch previous webinars.



Videos

View videos about RADx Tech/ATP programs, interviews with the NIBIB Director and more.

RADx Tech NIH Leads: Jill Heemskerk, Todd Merchak, Tiffani Lash, Mike Wolfson, Doug Sheeley, Bill Heetderks, Felicia Qashu, Tony Kirilusha, Mark Snyder, Andrew Weitz, Krishna Juluru, Taylor Gilliland, Rachael Fleurence, Matt McMahon, Jennifer Jackson, Ray MacDougall, Patty Wiley, Chris Cooper, David George

RADx: *Unexpected Opportunity*

April 24, 2020: \$1.5B to NIH
\$500 Million to NIBIB

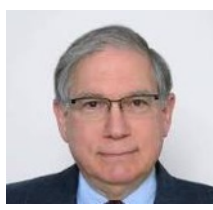
NIH Office of the Director



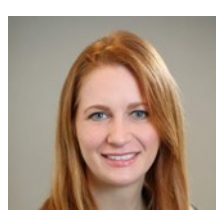
Francis Collins



Rachael Fleurance



Larry Tabak



Tara Schwetz

April 29

RADx Tech – \$500M

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – \$230M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

RADx Radical (RADx-Rad) – \$200M

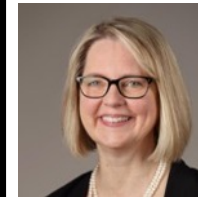
Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Underserved Populations (RADx-UP) – \$500M

Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

>12 NIH Institutes, Centers, and Offices

- 1) Expand COVID-19 Testing Technologies: *Number, Type and Access*
- 2) Optimize Performance: *Technologic and Operational; Match Community Needs*



Jill Heemskerk



Bruce Tromberg

National Institute of
Biomedical Imaging and
Bioengineering (NIBIB)



\$307 M Partnership



OASH



<https://www.nih.gov/research-training/medical-research-initiatives/radx>

RADx: *Leverage Existing Network (POCTRN)*

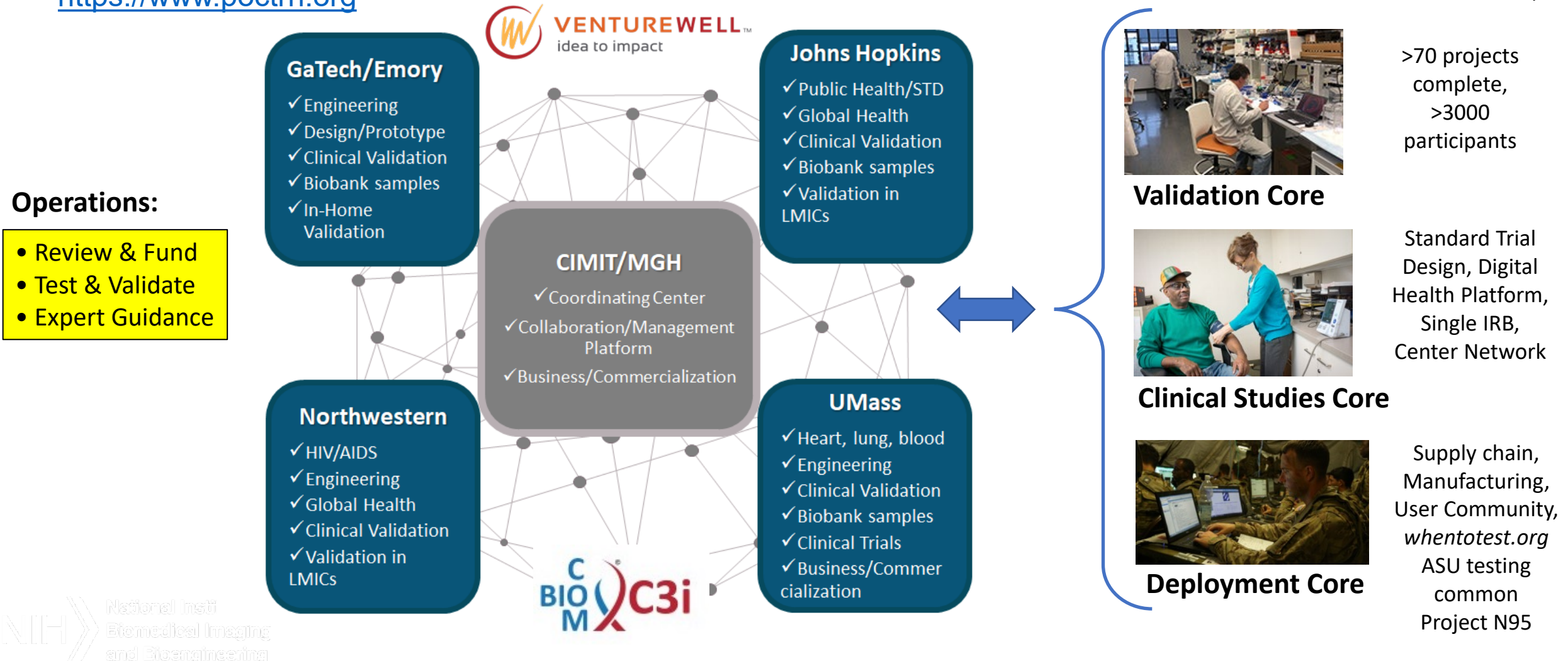
NIBIB Point of Care Tech Network: NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, ODP

Established 2007, Expanded 2020: >900 RADx experts & contributors
(USG, Academia, Industry, NFP)

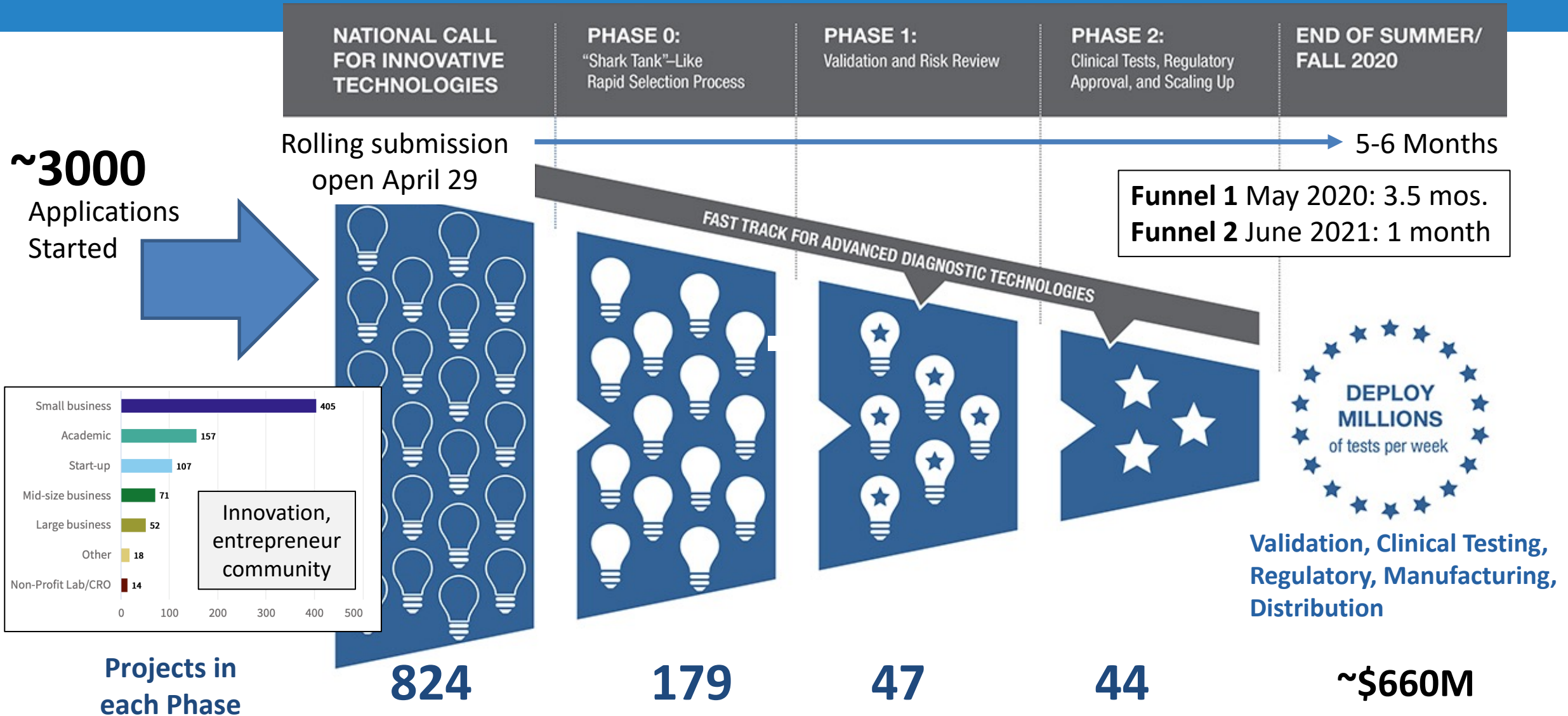
<https://www.poctrn.org>



Todd Merchak Tiffany Lash



RADx Tech Process: *Innovation Funnel*



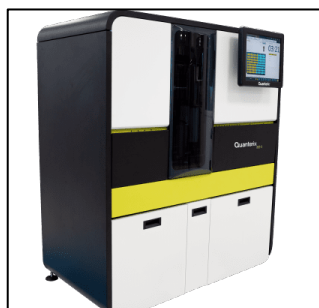


Mesa BioTech

Quidel QuickVue



Quanterix Simoa

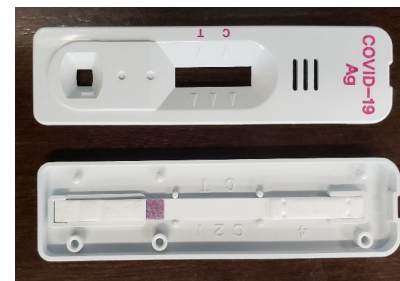


Quidel Sophia

Meridian



Genbody



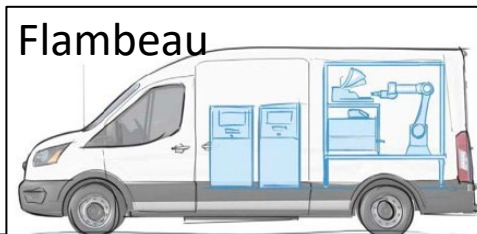
ANP



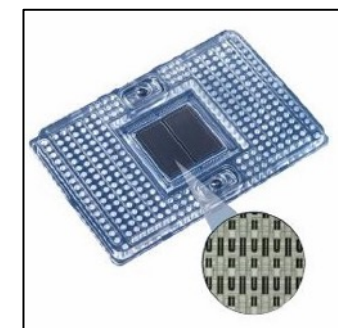
Ellume



Flambeau



Visby Medical



Fluidigm



Luminostics

Point of Care & Home

Visby	RTPCR
Mesa	RTPCR
MicroGem	RTPCR
Talis	RT-LAMP
Ubiquitome	RTPCR
Meridian	RTPCR
GenBody	An-LFA
Quidel Sophia	An-LFA
Quidel QuickView	An-LFA
Luminostics	An-LFA
ANP	An-LFA
Ellume	An-LFA
Xtrava	An-LFA
Qorvo	An-LFA
Mologic	An-LFA
Maxim	An-LFA
Saligistics	An-LFA
ANP	An-LFA
BD Veritor	An-LFA
Princeton Biomeditech	AN-LFA
Palogen	ASIC-nanopore
Detect	RT-LAMP
Uh-Oh Labs	RT-LAMP
Lumira Dx	An-μfluidic
Anavasi	RT-LAMP

Laboratory

Flambeau (+Saliva Direct)	PCR-mobile-lab
MatMaCorp	RTPCR-mini-lab
Fluidigm	RTPCR
Quanterix	SIMOA (An)
Minute Molecular	RTPCR
PathogenDx	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Gingko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
Aegis	RTPCR
Octant/UCLA	NGS/RTPCR

Lab Products

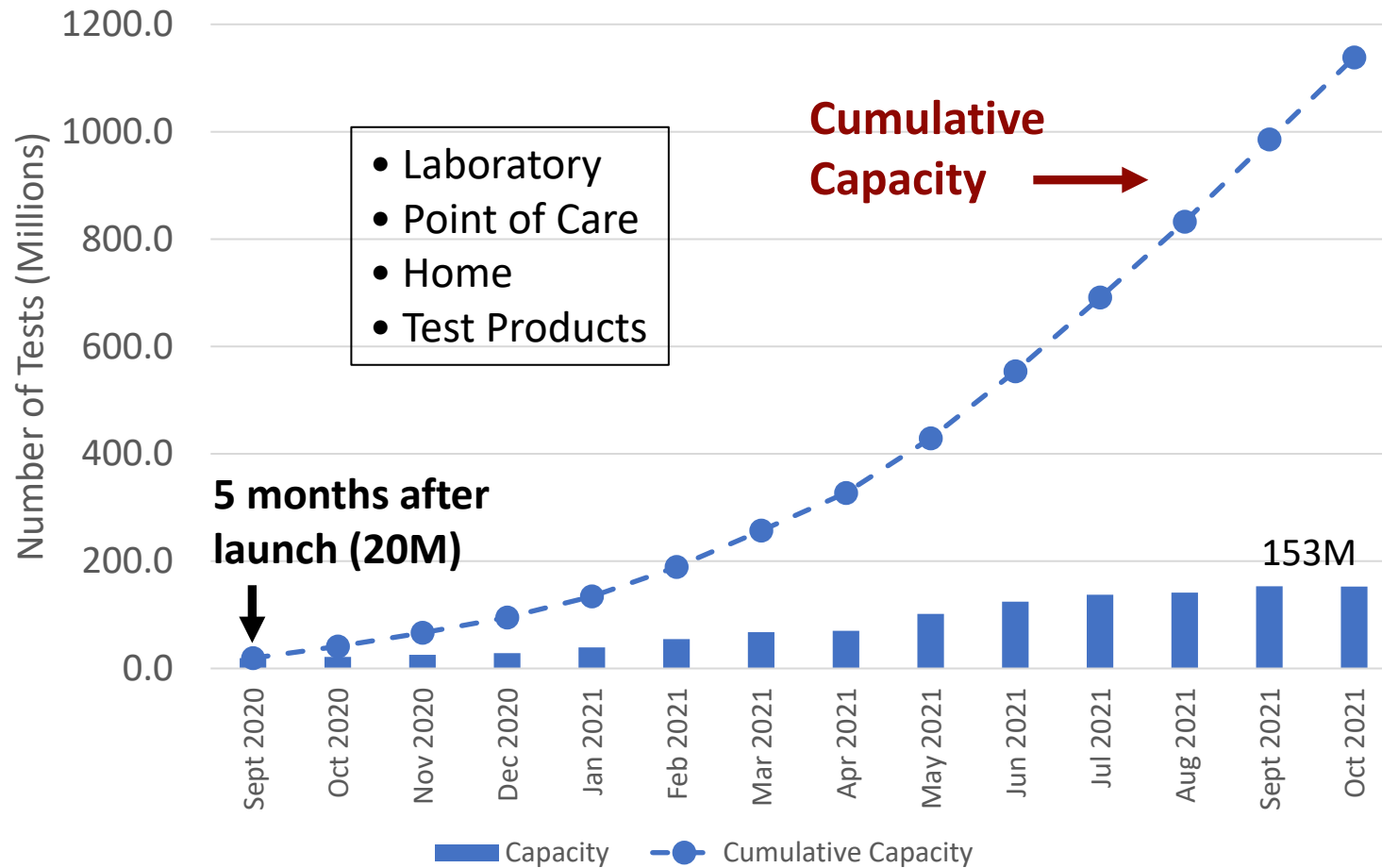
Mammoth Biosci	CRISPR
Ceres Nanosciences	Beads/Conc
Oasis	Saliva Collect
Yukon	Swabs

Tech

Labs

RADx Tech Impact: *Capacity thru October 2021*

Cumulative EUA Authorized Tests by Month



Major Milestones

- **1.14 billion capacity thru October 2021**
- **~5.1 M tests and products/day October 2021**
- **35 EUAs; 1st OTC EUA, 4 “at home”**

~\$1.1 Billion: *Special Congress Authorization*
(~\$600M in Phase 2)

~1.3 Billion: *Private Capital Raised*

<https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard>

Impact: *National Policy*

The Washington Post September 11, 2021

Democracy Dies in Darkness

Health

How at-home coronavirus testing is becoming part of Biden's plan for managing the pandemic



RADx tests
SYCT program

A Pitt County Health Department worker passes out at-home coronavirus test kits April 21 in Greenville, N.C. (Melissa Sue Gerrits for The Washington Post)

By [Derek Hawkins](#) and [Fenit Nirappil](#)

395

Work (OSHA): vaccine, weekly testing

Entertainment: show negative test

School: regular testing

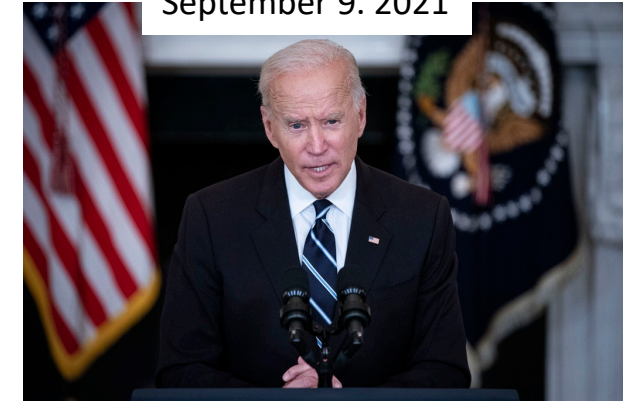
Procurement: \$3B OTC/POC tests, DPA

Retailers: sell OTC at cost, Medicaid reimbursement

Community: distribute OTC to high SVI regions

Pharmacy: Expand free POC access

September 9, 2021



When To Test



<https://whentotest.org>

SAY YES!
COVID TEST
KEEP OUR COMMUNITIES SAFE

<https://sayyescovidtest.org>

RADx Impact: *whentotest.org*



CALCULATOR
FOR INDIVIDUALS

CALCULATOR
FOR ORGANIZATIONS

RESOURCES ▾

ABOUT

CONNECT

NEWSROOM

STOP THE SPREAD OF COVID-19

FOR INDIVIDUALS

> START CALCULATOR

Don't spread COVID-19 in your community!
The When To Test Calculator for Individuals helps you decide whether you should consider getting tested.



> PROJECT  FIND TRUSTED TESTING SUPPLIES

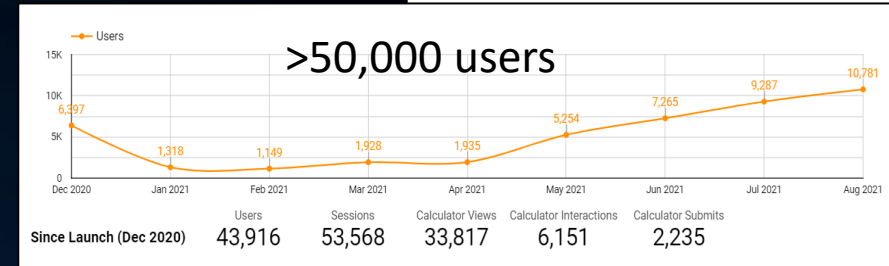
FOR ORGANIZATIONS

> START CALCULATOR

CDC guidelines provide a COVID-19 testing approach that applies to the population nationwide. The When To Test Calculator is designed to offer a more granular testing strategy for individual organizations based upon their unique mitigation strategies, level of compliance, and community prevalence.



>   COMPARE COVID-19 TEST BRANDS



- Vaccination rates
- R0 altered for Delta
- Pooling guidance
- K-12 playbook (CDC)
- Individual risk calculator
- Link purchase, guidance

SCHOOL LEADERS

> DOWNLOAD OUR K-12 PLAYBOOK

TESTING IMPLEMENTATION

> DOWNLOAD OUR COMPREHENSIVE GUIDE

LAB POOL TESTING

> DOWNLOAD OUR LAB POOL PLAYBOOK

RADx Tech Impact: *sayyescovidtest.org*

SAY YES! COVID TEST

KEEP OUR COMMUNITIES SAFE



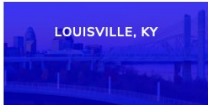
At-home testing for a healthier community.

Through Say Yes! COVID Test, the public health departments in select communities are offering access to free, rapid, at-home COVID-19 testing.

Select Your Community:

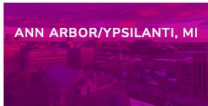
Current Communities

Distribution of free at-home COVID-19 tests is ongoing in these areas, for a limited time.

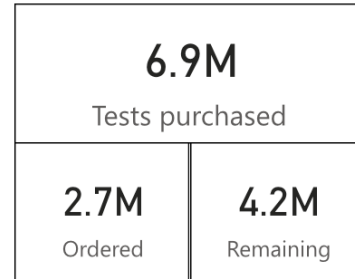


Completed Communities

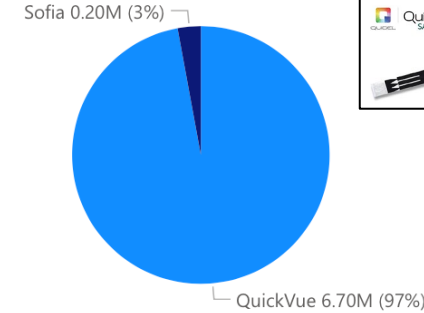
Test distribution has ended in these areas. Thank you for your participation!



This report reflects tests purchased directly by NIH to support specified projects. Tests purchased separately by awardees are not shown.



Tests Purchased



Tests ordered and remaining



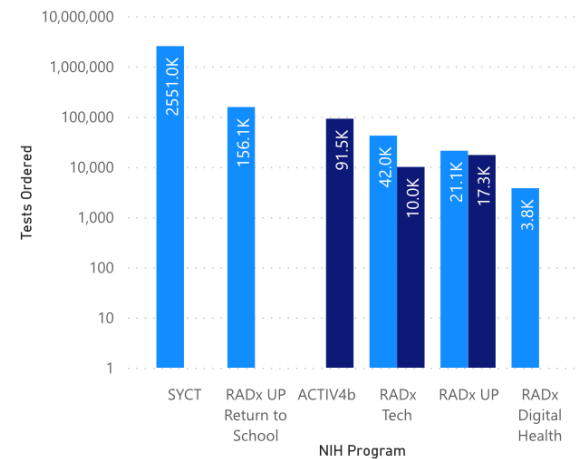
Remaining = Purchased - Ordered

Awardee

Activ Public / Private Partnership
 Duke University
 Johns Hopkins University
 Public Health Intervention
 Rush University
 San Diego State University
 U Massachusetts
 UIUC
 University of Chicago
 University of Hawaii
 University of New Mexico
 Vibrent Health

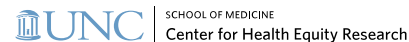
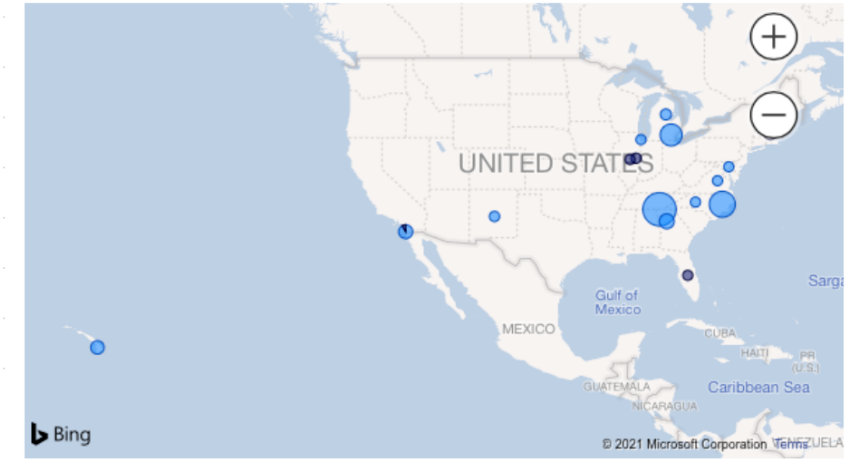
Tests Ordered by NIH Program and Test Type

Test Type ● QuickVue ● Sofia



Program locations

Test Type ● QuickVue ● Sofia



Rachael Fleurence



Bill Riley



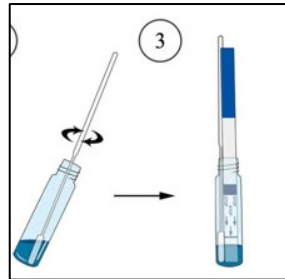
Mike Lauer

RADx Tech Impact: *Digital Health*



Andrew Weitz Krishna Juluru

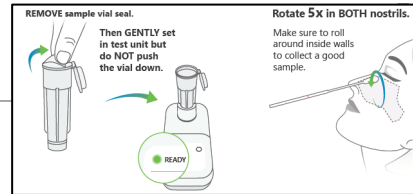
RADx POC Test



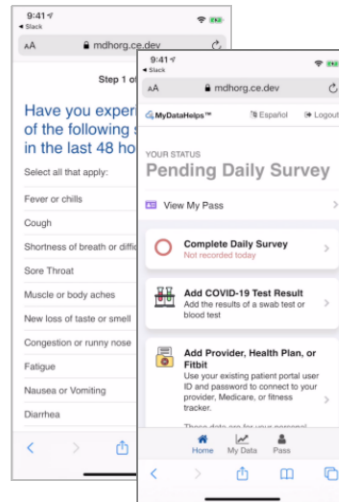
LFA



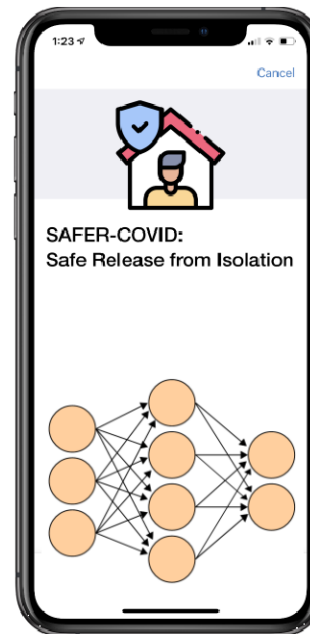
How to Use



Symptom Surveys



Cell
Phone
Reader



EHR & Claims

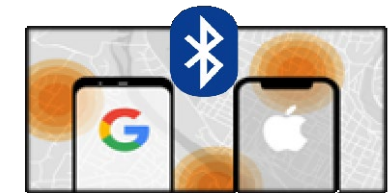


State and Federal

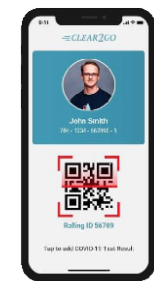


Need
Standards

Contact Tracing

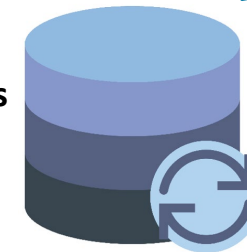


Health
status



e.g. VCI

Need
Standards



RADx Variant Task Force *(est Jan 2021)*

RADx Team

Richard Creager

Eric Lai

John Blackwood

Mia Cirrincione

Dale Gort

Emily Kennedy

D'lynne Plummer

Thomas Pribyl

Adam Samuta

Megan Shaw

Brian Walsh

Emory

Leda Bassit

Filipp Frank

Morgan Greanleaf

Wilbur Lam

Cangyuan Li

Eric Ortlund

Anuradha Rao

Raymond Schinazi

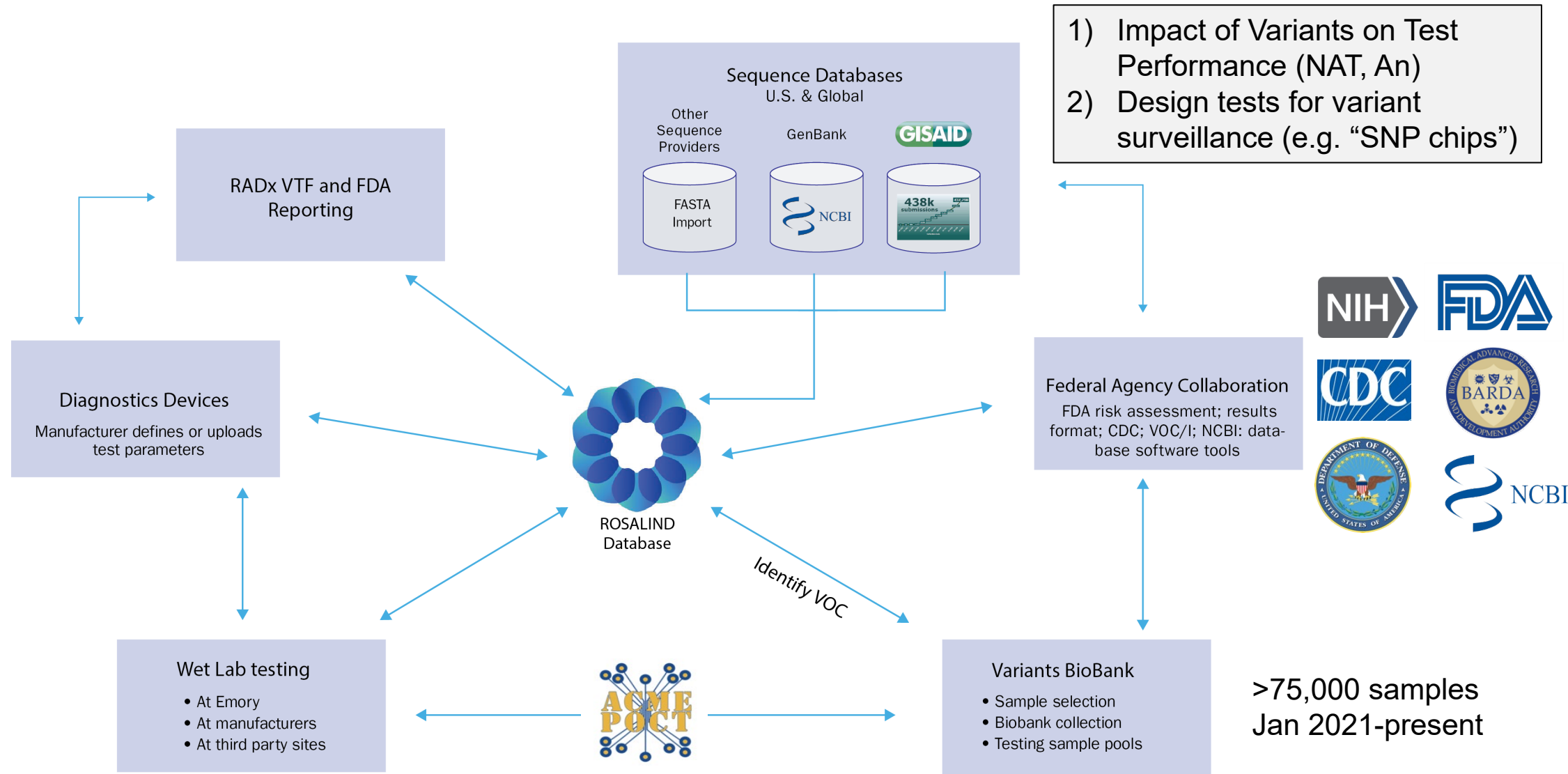
Allie Suessmith

Julie Sullivan

Thomas Vanderford

Univ of WA

Alex Greninger



RADx Variant Surveillance: “SNP Chip”

RADx Team

Richard Creager
Eric Lai

John Blackwood
Mia Cirrincione
Dale Gort
Emily Kennedy
D’lynne Plummer
Thomas Pribyl
Adam Samuta
Megan Shaw
Brian Walsh

Emory

Leda Bassit
Filipp Frank
Morgan Greanleaf
Wilbur Lam
Cangyuan Li
Eric Ortlund
Anuradha Rao
Raymond Schinazi
Allie Suessmith
Julie Sullivan
Thomas Vanderford

Univ of WA

Alex Greninger

“Project Rosa”



Helix, Thermo-Fisher, CDC

16 Markers:

- 1) *Positivity of sample*
- 2) *Lineage (>95% sens and spec all WHO variants + **Omicron**)*
- 3) *Mutations of biological interest*

Genotyping Validation (TaqMan, TF), 10k sample study, 4 weeks



**Submit FDA
EUA w/partner**

“SNP Chip” Advantages

Speed: no reflex, “real time” 1000s/day vs NGS ~4 weeks

Cost: CapX and price/test << NGS

Access: Adaptable to most labs: >50% vs 5% current NGS

Modify: New variant integration ~4-6 weeks

- 1) Impact of Variants on Test Performance (NAT, An)
- 2) Design tests for variant surveillance (e.g. “SNP chips”)

RADx Tech Future Directions

Lab RTPCR



ABL 7500

POC RTPCR

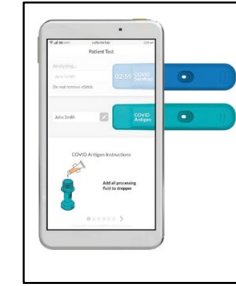


Mesa BioTech

POC An (LFA/reader)

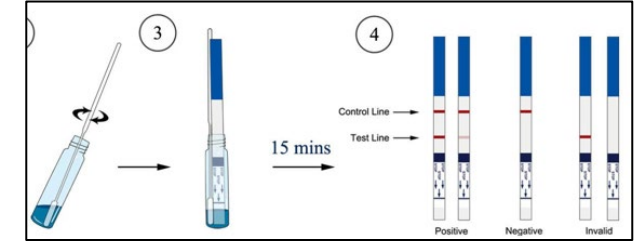


Quidel Sophia



Ellume

POC An (LFA/visual)



Dipstick LFA

Cost

\$\$\$\$

\$\$\$

Tech to Bridge the Gap?

\$\$

\$

Speed

hours

~30 min

<15 min

Sens/Spec

>90/95

>90/95

>90/95

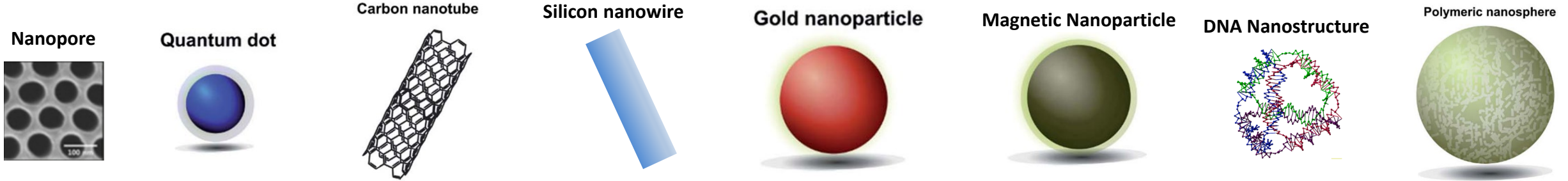
LOD

<10³ Cp/mL

<10³ Cp/mL

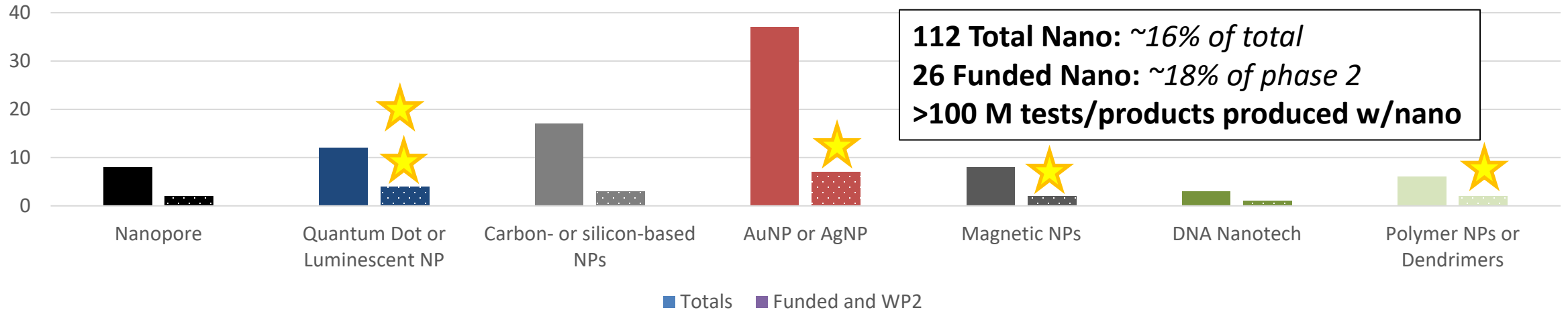
>10⁶ Cp/mL

New Tech: *Nano in RADx*



Images from Chudasama et al., *Chemical Science* 2016, Lim et al., *Nanoscale* 2015, Wikipedia

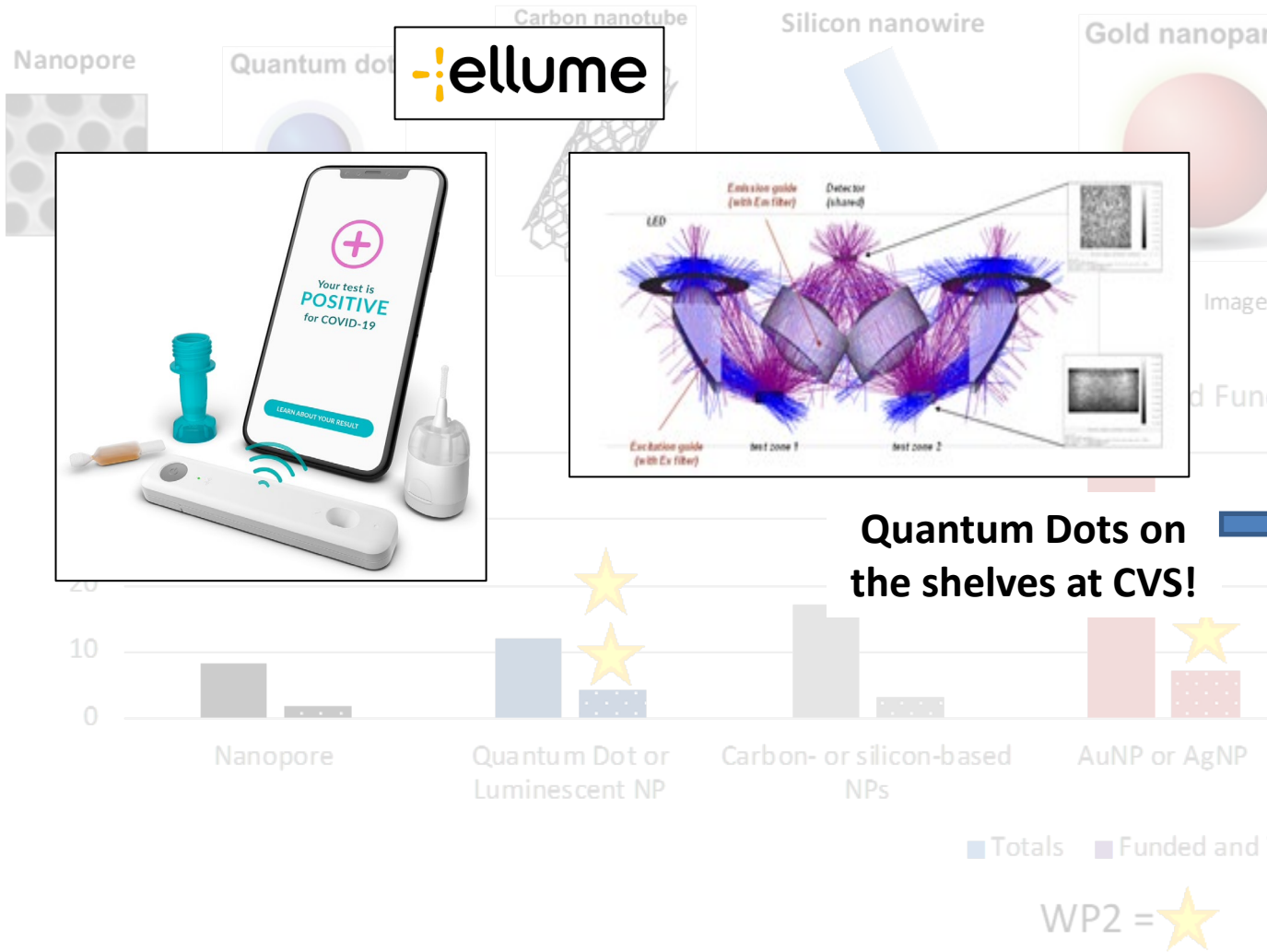
RADx-Tech Applications and Funded Proposals



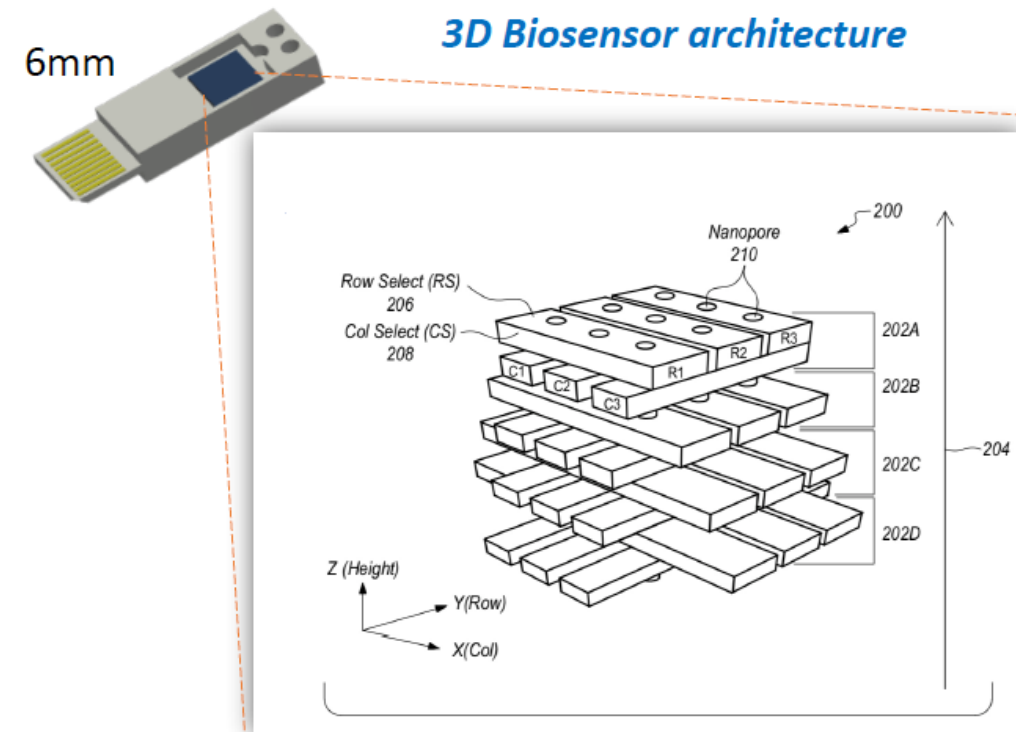
112 Total Nano: ~16% of total
26 Funded Nano: ~18% of phase 2
>100 M tests/products produced w/nano

WP2 = ★

NanoScience in RADx



3D Nano-electronic Biosensor

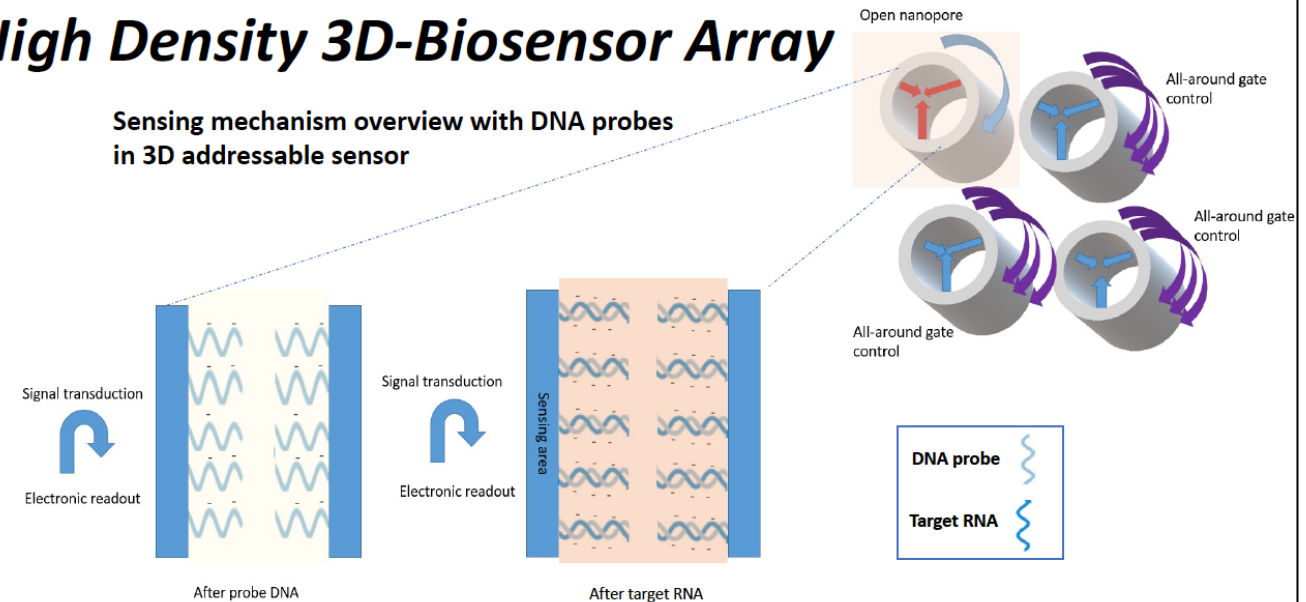


3D Flash Memory (V-NAND)

DNA Probes, Parallel Nucleic Acid Detection

High Density 3D-Biosensor Array

Sensing mechanism overview with DNA probes in 3D addressable sensor



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Ongoing Challenges

1) Reporting infrastructure

POLITICO

Inside America's Covid-reporting breakdown

Crashing computers, 3-week delays tracking infections, lab results delivered by snail mail: State officials detail a vast failure to identify hotspots quickly enough to prevent outbreaks



By ERIN BANCRO
08/15/2021 07:00 AM EDT



Illustrations by Glenn Harvey

There were too many cases to count.

Covid-19 was spreading rapidly throughout the United States, as cold winter weather began to drive people indoors, but the Centers for Disease Control and Prevention was flying blind: The state agencies that it relied on

Advertisement

Facebook
supports updated

2) Insufficient screening, surveillance

Nearly 5 out of 6 coronavirus cases were undetected in pandemic's early months

LA Times, June 25, 2021

Months into the pandemic, the U.S. had six times as many cases as reported, an N.I.H. study finds.

New York Times, June 24, 2021

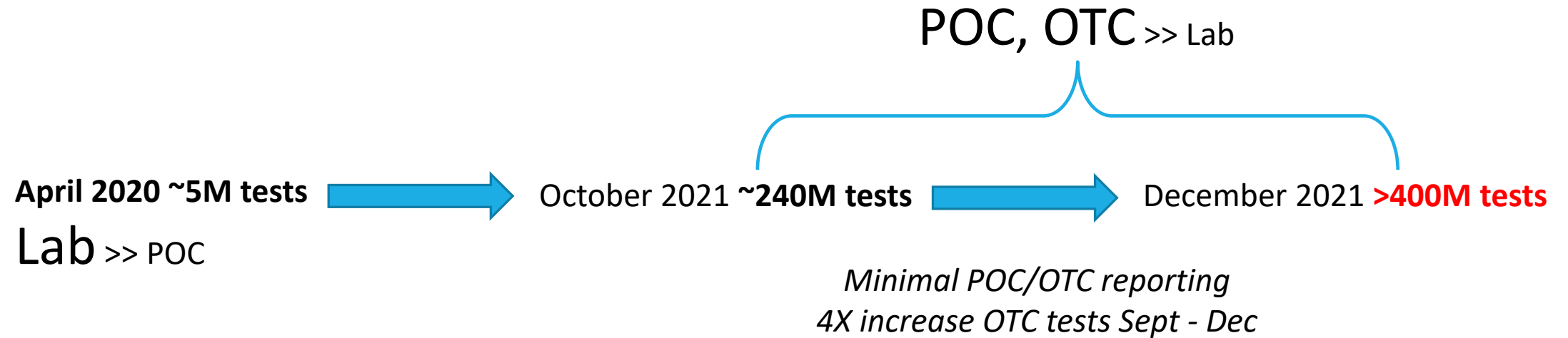
Nearly 17M Americans May Have Went Undiagnosed With COVID Last Year: Why These Cases Matter

International Business Times, June 24, 2021

K. Sadtler et al. Sci. Transl. Med, June 22, 2021

Ongoing Challenges

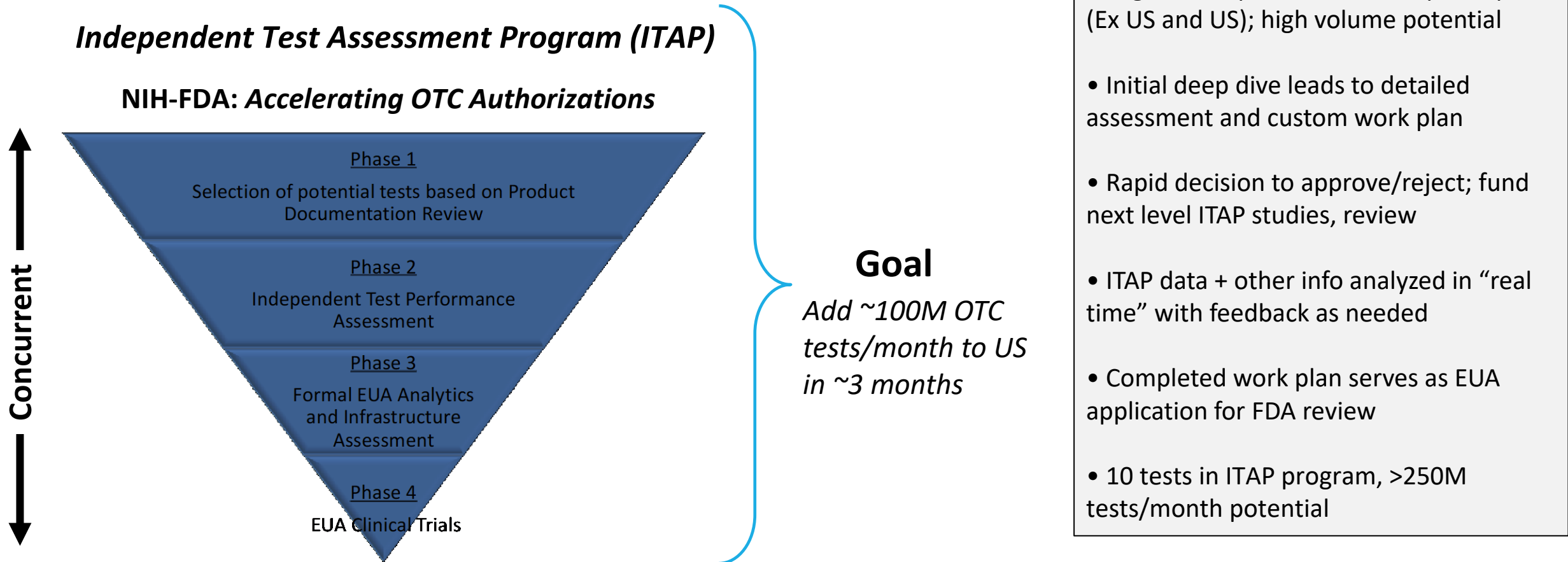
3) Paradigm Shift



Impact: *Guidance and policy decisions made based on lagging and incomplete test data*

Ongoing Challenges

3) Cost of Rapid OTC Tests: *demand >> supply*



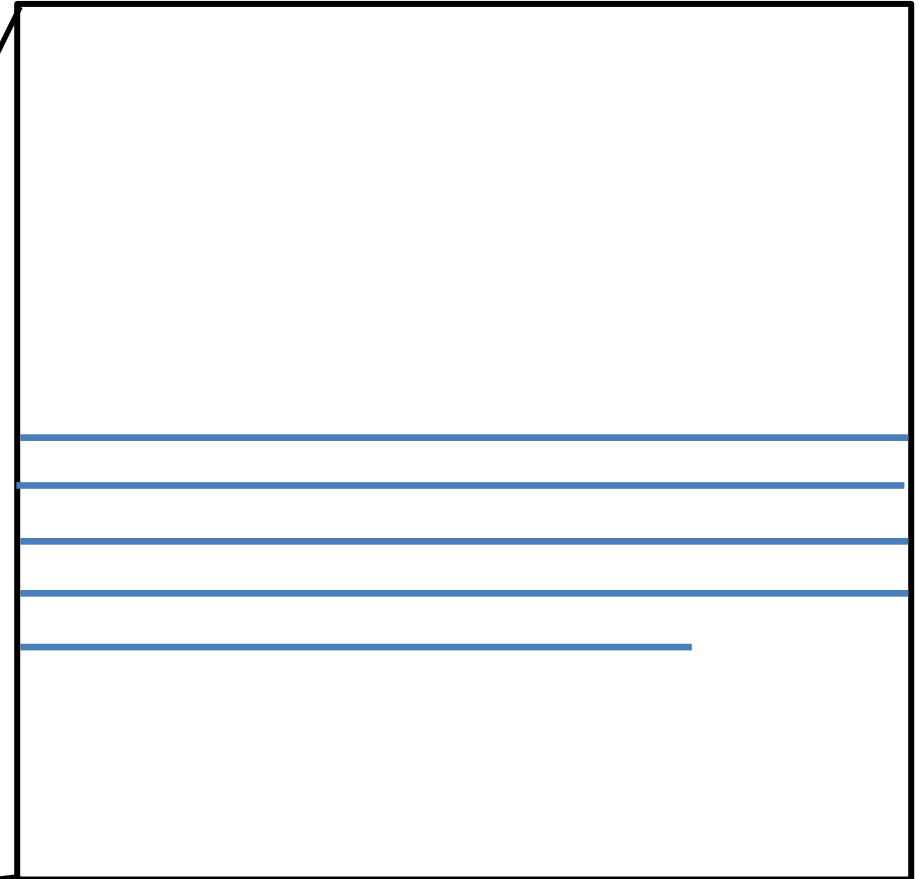
Ongoing Challenges

naturebiotechnology

 Check for updates

editorial

Call to action...



Summary

RADx investment: *accelerated decades of in vitro diagnostic tech for COVID*

- **Better, accessible fast tests:** Inexpensive OTC/POC; some w/ laboratory test performance
- **Multiplex tests:** COVID, flu A/B, RSV, etc. for differential Dx (*POC, lab*)
- **Fast, accurate, cost-effective surveillance:** Genotyping w/Informatics, (*lab, POC*)
- **Real Time Reporting:** Modernize, expand digital health networks and communication/reporting
- **Low Cost OTC:** Increase supply, automation, distribution channels

Future: *Leverage RADx process, tech, and networks for other pathogens, preparedness, precision medicine*